

CHILDRENS TUSSIN DM- childrens tussin dm liquid
KINGSTON PHARMA LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Children's Tussin DM

Active Ingredient: Active Ingredient: Dextromethorphan HBr 5mg, Guaifenesin 100mg (in each 5 mL)

Purpose:

Cough suppressant

Expectorant

- temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold
- helps loosen phlegm (mucus) and thin bronchial secretions to coughs more productive

DO NOT USE IF PRINTED SEAL OVER IS TORN OR MISSING

Warnings:

Do not use if a child who is taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions or parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.

Ask a doctor before use if the child has

- Cough that occurs with too much phlegm (mucus)
- Persistent or chronic cough such as occurs with asthma

Stop use and ask doctor if cough lasts more than 7 days, comes back, or occurs with fever, rash, or persistent headache. These could be signs of a serious illness.

Keep this and all drugs out of the reach of children. In case of overdose, seek professional assistance or contact a Poison control center right away.

Directions:

- This product does not contain directions or complete warnings for adult use.
- Use only enclosed dosing cup provided.
- Do not take more than 6 doses in any 24-hour period.
- **Children 6 years to under 12 years:** 5 mL – 10 mL taken every 4 hours.
- **Children 4 years to under 6 years:** 2.5 mL – 5 mL taken every 4 hours.
- **Children under 4 years:** do not use.

Other information

- each teaspoon contains: sodium 4 mg
- store at 20°-25°C (68°-77°F)

Inactive ingredients

Anhydrous citric acid, Artificial & Natural flavors, FD&C Blue#1, FD&C red 40, Sucralose, Glycerin, Polyethylen Glycol, Propylene Glycol, Purified Water, Sodium Citrate, Sodium Benzoate

(packs: 4oz) Kingston NDC# 71027-036-04

Manufactured by: Kingston Pharma LLC

5 County Route 42

Massena, NY 13662



TUSSIN DM

Cough Suppressant /
Expectorant

Compare To Active Ingredients in
Children's Robitussin Cough & Ches
+ Congestion DM ®



Children's Cough
& Ches + Congestion
TUSSIN DM
Ages 6 & Over

Dextromethorphan HBR
(Cough Suppressant)
Guaifenesin
(Expectorant)

Controls Cough
For Adults & Children

- Alcohol Free Cough Formula
- Helps Loosen Phlegm (Mucus)
& Relieve Chest Congestion

2 FL OZ (60 mL)

*This product is not manufactured or
distributed by Whitehall - Robins Healthcare
distributors of Robitussin DM®

Drug Facts (continued)

Directions

- Do not take more than 6 doses in a 24-hour period
- Repeat dose every 4 hours while symptoms last

| AGE | DOSE |
|-----------------------------------|--------------------------|
| Children Under 6 Years | Do Not Use |
| Children 6 to Under 12 Years | 5 - 10 ml every 4 Hours |
| Adults & Children 12 Years & Over | 10 - 20 ml every 4 Hours |

Inactive ingredients

citric acid, dextrose**, flavor FD&C red #40, glucose**, glycerin, high fructose corn syrup, menthol, purified water, saccharin sodium, sodium benzoate

Other information

- Store at 15-30°C (59-86°F)
- Protect from freezing
- Free dosage cup
- Alcohol free
- Protect from light
- Each teaspoon 5mL contains: sodium 3mg

**contains one or more of these ingredients

QUESTIONS AND COMMENTS?
+1 888-588-8511

Distributed by:
Globela Pharma LLC.
West New York, NJ - USA 07093
www.globelapharma.com

Compare To Active Ingredients in
Children's Robitussin Cough & Ches
+ Congestion DM ®



Children's Cough
& Ches + Congestion
TUSSIN DM
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TAMPER EVIDENT: Do not use this product if
printed inner cap seal is broken or missing.

Drug Facts

| Active ingredients | Purpose |
|---|-------------------|
| (In each 5 mL.) Guaifenesin USP 100 mg | Expectorant |
| Dextromethorphan HBr USP 5 mg | Cough Suppressant |

Uses

temporarily relieves cough due to minor throat and bronchial irritation as may occur with cold. It loosens phlegm (mucus) and thin bronchial secretions to make coughs more productive

Warnings

Do not use if you are now taking a prescription monamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease) or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains MAOI, ask a doctor or a pharmacist before taking this product.

Ask a doctor before use if

- cough that occurs with too much phlegm (mucus)
- cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis or emphysema

Stop use and ask doctor if

- cough lasts more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition.

If pregnant or breast feeding ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Lot
Exp

CHILDRENS TUSSIN DM

childrens tussin dm liquid

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:71027-032 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------------------|-------------------|
| DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 5 mg in 5 mL |
| GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) | GUAIFENESIN | 100 mg in 5 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-----------------|
| ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| WATER (UNII: 059QF0KO0R) | |
| SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|-----------------------------|---------------------------|
| 1 | NDC:71027-032-04 | 1 in 1 CARTON | 03/01/2017 | |
| 1 | | 118 mL in 1 BOTTLE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| OTC monograph final | part341 | 03/01/2017 | |

Labeler - KINGSTON PHARMA LLC (080386521)**Registrant** - KINGSTON PHARMA LLC (080386521)**Establishment**

| Name | Address | ID/FEI | Business Operations |
|---------------------|----------------|---------------|----------------------------|
| KINGSTON PHARMA LLC | | 080386521 | manufacture(71027-032) |

